



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22CX; Docket No. CDC-2022-0031]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), as part of its continuing effort to reduce public burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Preferences for Longer-Acting Preexposure Prophylaxis (LA-PrEP) Methods Among Persons in U.S. Populations at Highest Need: A Discrete Choice Experiment. The proposed project is designed to understand preferences for LA-PrEP products for HIV prevention among potential users and providers.

DATES: CDC must receive written comments on or before [INSERT
DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2022-0031, by either of the following methods:

- Federal eRulemaking Portal: [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [regulations.gov](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition,

the PRA also requires federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Preferences for Longer-Acting Preexposure Prophylaxis (LA-PrEP) Methods Among Persons in U.S. Populations at Highest Need: A Discrete Choice Experiment - New - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The 2022-2025 National HIV/AIDS Strategy includes a goal of increasing pre-exposure prophylaxis (PrEP) coverage to 50 percent among persons with indications, from a 2017 baseline of 13.2 percent. Despite successes in development and scale up of daily oral PrEP as a biomedical HIV prevention product, studies consistently show obstacles to its uptake and continuation. The Centers for Disease Control and Prevention (CDC) and its partners must engage in early planning for the implementation of longer-acting PrEP (LA-PrEP) agents to help achieve the U.S. Ending the HIV Epidemic (EHE) goal of reducing incident HIV infections by 90 percent by 2030. Understanding providers' and priority populations' preferences for different LA-PrEP agents, and perceived advantages and disadvantages of each product, will be critical to estimating future uptake and use of the various products that are recently or soon likely to become available for prescription.

The goal of this study is to understand preferences for LA-PrEP products for HIV prevention among potential users and

providers, including product characteristics and other service delivery factors that may facilitate or hinder future uptake of these products. In cooperation with partners, CDC will conduct a discrete choice experiment (DCE) among providers and potential users of LA-PrEP products to elicit their preferences for characteristics of LA-PrEP and delivery programs to maximize uptake of LA-PrEP among people in need of HIV prevention methods. Results from this experiment will be used to identify factors key to adoption and implementation of each product and increase implementation efficiency by identifying strategies to support decision making and address potential challenges.

The study design is a cross-sectional, online survey comprised of a DCE and additional questions to directly elicit participant preferences and gather data on socioeconomic, behavioral, and attitudinal factors. DCE methods are based on the principle that products or services are evaluated through their multiple features or 'attributes,' and that an individual's choice of a product or service is a function of the utility of each attribute option or 'level.' Attributes and their corresponding levels are chosen to represent the features of medications, devices, and healthcare services that are relevant to a healthcare decision.

The proposed information collection will include two separate DCE surveys: one for priority populations and one for clinicians. The survey uses an experimental design to combine levels from each attribute into hypothetical product profiles

and to pair profiles into choice tasks. The experimental design will be split into several blocks or versions. Each equally sized block will have 8-12 questions, and questions will not be repeated across blocks. Participants will be randomly assigned to a block and will see only one block when completing the survey instrument.

The study's target population includes persons ages 18 and older who either 1) prescribe PrEP or 2) are in the following priority population groups selected because they have the highest rates of HIV acquisition and are in need for HIV prevention services:

- Gay, bisexual, and other men who have sex with men subdivided by race/ethnicity:
 - Black / African American,
 - Hispanic / Latino, or
 - White;
- Black / African American heterosexual persons subdivided by biological sex:
 - Men or
 - Women;
- Transgender women; and
- Persons who inject drugs.

To be eligible for the study, potential participants in each of the priority population groups must be 18 years of age or older, living without HIV, and meet the U.S. Public Health Service (USPHS) indications for offering PrEP as described in the 2021 USPHS Clinical Practice Guidelines.

The study sample will be recruited from cities with high numbers of annual HIV diagnoses within the 57 priority jurisdictions identified as part of the EHE initiative. Participants will be randomly assigned to a block when they are sent their unique DCE survey link and will only complete the set of choice tasks in that block. Throughout the study, we will closely monitor recruitment and data collection to ensure that screening criteria are being met, key demographic groups are adequately represented, and survey completion rates are acceptable.

Participation is voluntary. For this study, CDC intends to screen approximately 9,200 participants and enroll 1,840 participants. CDC estimates that approximately 15 percent of enrolled participants will be removed from the analysis due to fraud or incomplete data, resulting in a final analysis sample size of 1,600 participants. At 25 minutes per survey and 10 minutes per combined screening and consent, CDC requests approval for an estimated 2,341 annualized burden hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

(Type of) Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
Black/African American, Hispanic/Latino, or White men who are gay, bisexual or have sex with men,	Screening & Consent	3,450	1	10/60	587
	Survey	690	1	25/60	290

ages 18+ in the United States					
Black/African American Heterosexual Cisgender Men or Women, ages 18+, in the United States	Screening & Consent	2,300	1	10/60	391
	Survey	460	1	25/60	194
Transgender Women, ages 18+, in the United States	Screening & Consent	1,150	1	10/60	196
	Survey	230	1	25/60	97
Persons who inject drugs, ages 18+, in the United States	Screening & Consent	1,150	1	10/60	196
	Survey	230	1	25/60	97
Clinical providers who prescribe PrEP, in the United States	Screening & Consent	1,150	1	10/60	196
	Survey	230	1	25/60	97
Total					2,341

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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